UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/582,292	05/31/2007	**Chawnshang Chang**	24376.18.8402	1600

53449 7590 06/05/2009

PATENT CORRESPONDENCE
ARNALL GOLDEN GREGORY LLP
171 17TH STREET NW
SUITE 2100
ATLANTA, GA 30363

EXAMINER	
HARRIS, ALANA M	
ART UNIT	**PAPER NUMBER**
1643	

MAIL DATE	DELIVERY MODE
06/05/2009	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/582,292	CHANG, CHAWNSHANG	
	Examiner	Art Unit	
	Alana M. Harris, Ph.D.	1643	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *1* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-52* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-52* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

Election/Restrictions

1. Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group I, claim(s) 1-5, drawn to a method of screen a subject for breast cancer comprising assaying for the presence of androgen receptor protein. Claims 1-5 will be examined with this Group to the extent an antibody is used to detect the androgen receptor.

Group II, claim(s) 1-10, drawn to a method of screen a subject for breast cancer comprising assaying for the presence of androgen receptor mRNA. Claims 1-5 will be examined with this Group to the extent a nucleic acid probe is used to detect the androgen receptor.

Group III, claim(s) 11-14, 16, 18, 23 and 24, drawn to a method of treating cancer comprising administering an androgen receptor inhibitor, wherein the inhibitor comprises ARA67. Claims 11, 12, 14, 16, 18, 23 and 24 will be examined with the instant Group to the extent ARA67 is administered to a subject.

Group IV, claim(s) 11, 12, 14-16, 18, 23 and 24, drawn to a method of treating cancer comprising administering an androgen receptor inhibitor, wherein the inhibitor comprises GSK2B. Claims 11, 12, 14, 16, 18, 23 and 24 will be examined with the instant Group to the extent GSK2B is administered to a subject.

Group V, claim(s) 11, 12, 14, 16-18, 23 and 24, drawn to a method of treating cancer comprising administering an androgen receptor inhibitor, wherein the inhibitor comprises hRad9. Claims 11, 12, 14, 16, 18, 23 and 24 will be examined with the instant Group to the extent hRad9 is administered to a subject.

Group VI, claim(s) 11 and 19-24, drawn to a method of treating cancer comprising administering an androgen receptor inhibitor, wherein the inhibitor is a functional nucleic acid, SEQ ID NO: 11. Claims 11, 23 and 24 will be examined with the instant Group to the extent a siRNA is administered to a subject.

Group VII, claim(s) 25-30, drawn to a method of screen a composition for the ability to modulate androgen receptor (AR) activity comprising administering the compound to a system.

Group VIII, claim(s) 31 and 32, drawn to a composition for inhibiting androgen receptor activity comprising a molecule, which is not SEQ ID NO: 1. *NOTE:* Claim 32 reading on ARA67 will be examined *only* with the instant Group to the extent the species elected is a protein/peptide.

Group IX, claim(s) 33 and 34, drawn to drawn to a composition for inhibiting androgen receptor activity comprising a molecule, which is not SEQ ID NO: 7. *NOTE:* Claim 33 reading on hRad9 will be examined *only* with the instant Group to the extent the species elected is a protein/peptide.

Group X, claim(s) 35-37, drawn to a composition inhibiting androgen receptor activity comprising a functional nucleic acid, a siRNA comprising SEQ ID NO: 11.

Group XI, claim(s) 38, 41 and 44-46, drawn to a composition for inhibiting androgen receptor activity comprising an antibody, wherein the molecule competes with ARA67 for binding to AR and is not SEQ ID NO: 1. Claims 38 and 41 will be examined with Group XI to the extent the composition comprises an antibody.

Group XII, claim(s) 38, 41, 47 and 48, drawn to a composition for inhibiting androgen receptor activity comprising a functional nucleic acid, wherein the molecule competes with ARA67 for binding to AR and is not SEQ ID NO: 1. Claims 38 and 41 will be examined with Group XII to the extent the composition comprises a functional nucleic acid.

Group XIII, claim(s) 39 and 42, drawn to a composition for inhibiting androgen receptor activity comprising an antibody, wherein the molecule competes with hRad9 for binding to AR and is not SEQ ID NO: 7. Claims 39 and 42 will be examined with Group XIII to the extent the composition comprises an antibody.

Group XIV, claim(s) 39 and 42, drawn to a composition for inhibiting androgen receptor activity comprising a molecule, wherein the molecule competes with hRad9 for binding to AR and is not SEQ ID NO: 7. Claims 39 and 42 will be examined with Group XIV to the extent the composition comprises a functional nucleic acid.

Group XV claim(s) 40, drawn to a composition for inhibiting androgen receptor activity comprising an antibody, wherein the molecule competes with GSK2B for binding to AR and is not SEQ ID NO: 5. Claim 40 will be examined with Group XV to the extent the composition comprises an antibody.

Group XVI claim(s) 40, drawn to a composition for inhibiting androgen receptor activity comprising a functional nucleic acid, wherein the molecule competes with GSK2B for binding to AR and is not SEQ ID NO: 5. Claim 40 will be examined with Group XVI to the extent the composition comprises a functional nucleic acid.

Group XVII, claim(s) 43, drawn to a composition for inhibiting androgen receptor activity comprising an antibody, wherein the composition binds AR and is not SEQ ID NO: 5. Claim 43 will be examined with the instant Group to the extent the composition comprises an antibody.

Group XVIII, claim(s) 43, drawn to a composition for inhibiting androgen receptor activity comprising a functional nucleic acid, wherein the composition binds AR and is not SEQ ID NO: 5. Claim 43 will be examined with the instant Group to the extent the composition comprises a functional nucleic acid.

Group XIX, claim(s) 49, drawn to a compound produced by the method of screening a compound for the ability to modulate AR activity comprising administering the compound to a system.

Group XX, claim(s) 50, drawn to drawn to a compound produced by the method of screen a compound for ability to modulate AR activity comprising administering compound that decreases the amount of nuclear AR.

Group XXI, claim(s) 51, drawn to drawn to a compound produced by the method of screen a compound for ability to modulate AR activity comprising administering compound that decreases the amount of phosphorylated AR.

Group XXII, claim(s) 52, drawn to drawn to a compound produced by the method of screen a compound for ability to modulate AR activity comprising administering compound that decreases the amount of N-terminus AR interacting with the C-terminus of AR.

2. The inventions listed as Groups I-XXII do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons: Fujimoto et al. (Laboratory Investigation 80(9): 1465-1471, September 2000) discloses assaying extramammary paget's disease (EMPD) surgical specimens for the presence of AR with an antihuman AR monoclonal antibody, see page 1469, Materials and Methods section. Moreover, Moinfar et al. (Cancer 98(4): 703-711, August 15, 2003) discloses immunohistochemical assays for AR in samples of breast carcinomas with antibodies, see page 704, Materials and Methods section. Therefore, the technical feature recited in claim 1 is not special. Accordingly, the groups are not so linked as to form a single general concept under PCT Rule 13.1.

3. Applicants are reminded with the election of any one of Groups VII-IX and XIX Applicants are to further elect one of the species listed below in the following paragraphs.

4. This application contains claims directed to more than one species of the generic invention. These species are deemed to lack unity of invention because they are not so linked as to form a single general inventive concept under PCT Rule 13.1.

The species are as follows:

a. ARA67;

b. GSK2B; and

c. hRad9.

Applicant is required, in reply to this action, to elect a single species to which the claims shall be restricted if no generic claim is finally held to be allowable. The reply must also identify the claims readable on the elected species, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered non-responsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

The claims are deemed to correspond to the species listed above in the following manner:

The claims read on different compounds which modulate the different and distinct proteins.

The following claim(s) are generic: 25-30 and 49.

The species listed above do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, the species lack the same or corresponding special technical features for the following reasons: each protein is unique and distinct in structure and interacting proteins.

5. This application contains claims directed to more than one species of the generic invention. These species are deemed to lack unity of invention because they are not so linked as to form a single general inventive concept under PCT Rule 13.1.

The species are as follows:

a. protein/peptide;

b. antibody; and

c. functional nucleic acid.

Applicant is required, in reply to this action, to elect a single species to which the claims shall be restricted if no generic claim is finally held to be allowable. The reply must also identify the claims readable on the elected species, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered non-responsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form

or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

The claims are deemed to correspond to the species listed above in the following manner:

The claims read on different compounds which modulate the different and distinct proteins.

The following claim(s) are generic: 31 and 33.

The species listed above do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, the species lack the same or corresponding special technical features for the following reasons: each molecule is unique and distinct in structure, composition and modes of implementation.

6. Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species or invention to be examined even though the requirement may be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention.

The election of an invention or species may be made with or without traverse. To preserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse.

7. The Examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and the product claims are subsequently found allowable, withdrawn process claims that depend from or otherwise require all the limitations of the allowable product claim will be considered for rejoinder. All claims directed to a nonelected process invention must require all the limitations of an allowable product claim for that process invention to be rejoined.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103 and 112. Until all claims to the elected product are found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowable product claim will not be rejoined. See MPEP § 821.04(b). Additionally, in order to retain the right to rejoinder in accordance with the above policy, applicant is advised that the process claims should be amended during prosecution to require the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder**. Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the Examiner before the patent issues. See MPEP § 804.01.

8. Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Alana M. Harris, Ph.D. whose telephone number is (571)272-0831. The Examiner works a flexible schedule, however she can normally be reached Monday through Saturday, 7:30 am to 6:30 pm with alternate Fridays off.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Larry R. Helms, Ph.D. can be reached on (571) 272-0832. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Alana M. Harris, Ph.D.
3 June 2009
/Alana M. Harris, Ph.D./
Primary Examiner, Art Unit 1643